UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

UNITED STATES OF AMERICA, Plaintiff, v. INVACARE CORPORATION, a corporation, GERALD B. BLOUCH, and RONALD J. CLINES, individuals, Defendants.	)	No. 1:12cv3086 CONSENT DECREE FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction against Invacare Corporation ("Invacare"), a corporation, and Gerald B. Blouch and Ronald J. Clines, individuals (collectively, "Defendants"), and Defendants, having appeared and having consented to entry of this Decree without contest, without admitting or denying the allegations in the Complaint, and disclaiming any liability in connection herewith, and before any testimony has been taken, and the United States having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. For the purposes of this Decree, (a) the "Corporate facility" is defined as

Invacare's corporate headquarters, located at One Invacare Way, Elyria, OH 44035, and (b) the "Taylor Street facility" is defined as the facility located at 1200 Taylor Street, Elyria, OH 44035.

3. This Decree applies to all manual and power wheelchairs, wheelchair components, and wheelchair sub-assemblies that are designed, manufactured, processed, packed, repacked, labeled, and held at and distributed from, the Taylor Street facility ("Taylor Street devices"). This Decree requires the Taylor Street facility to comply with the medical device quality system regulation and current good manufacturing practice requirements set forth in 21 C.F.R. Part 820, and with the medical device reporting requirements set forth at 21 C.F.R. Part 803 that apply to Taylor Street devices.

4. This Decree requires the Corporate facility to: (a) assure that Taylor Street devices, powered beds, and powered bed components (hereinafter, collectively, "subject devices") are designed in compliance with the medical device quality system regulation and current good manufacturing practice requirements set forth in 21 C.F.R. Part 820, and (b) comply with the medical device reporting requirements set forth at 21 C.F.R. Part 803 with respect to the subject devices.

5. Upon entry of this Decree, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of the contents of this Decree by personal service or otherwise, are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly designing, manufacturing, processing, packing, repacking, labeling, holding, distributing, importing into or exporting from the United States of America, at or from

the Corporate or Taylor Street facilities, any subject device unless and until:

A. Defendants' methods, facilities, and controls used to design, manufacture, process, pack, label, hold, and distribute the subject devices, at the Corporate and Taylor Street facilities, are established, operated, and administered in compliance with 21 U.S.C. § 360j(f)(1) and the Quality System regulation set forth in 21 C.F.R. Part 820.

B. Defendants select and retain at their expense an independent person or persons (the "Expert") to conduct inspections of (i) Defendants' quality system and medical device reporting operations conducted at the Corporate facility with respect to the subject devices, and (ii) all operations at the Taylor Street facility with respect to the Taylor Street devices (collectively, "Defendants' operations") and to review Defendants' procedures and methods for designing the subject devices, and for manufacturing, processing, packing, repacking, labeling, holding, and distributing the Taylor Street devices, to determine whether their methods, facilities, and controls are operated and administered in conformity with the Federal Food, Drug, and Cosmetic Act ("the Act"), its implementing regulations, and this Decree. The Expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within ten (10) calendar days of retaining such Expert.

C. The Expert shall perform comprehensive inspections of Defendants' operations at the Corporate and Taylor Street facilities and provide three written reports to FDA. In the first report, the Expert shall identify what documents and systems he or she has reviewed and certify in writing (i) that he or she has inspected Defendants' qualification and validation

documentation for equipment and processes used to manufacture parts, components, accessories, and subassemblies; and (ii) that Defendants' qualification and validation procedures and documentation for equipment and processes at the Taylor Street facility comply with the Act, its implementing regulations, and this Decree.

D. Within thirty (30) days after FDA's receipt of a report submitted by the Expert under paragraph 5(C), FDA shall notify Defendants in writing whether Defendants appear to be in compliance with the equipment and process validation requirements set forth in paragraph 5(C). Upon receipt of FDA's written notification that Defendants appear to be in compliance with paragraph 5(C), Defendants may resume manufacturing and distributing parts, components, accessories, and subassemblies to Invacare facilities other than the Taylor Street or Corporate facilities for further manufacturing or to provide service as permitted under paragraph 6(J).

E. In the Expert's second report, he or she shall certify in writing that he or she has inspected all of Defendants' procedures relating to the design control systems used at the Corporate and Taylor Street facilities, including but not limited to, systems used to establish and implement adequate design and development plans, inputs, outputs, design reviews, verification, validation, risk analyses, and design change controls. The foregoing Expert report shall also include, at a minimum, a review of the Design History Files for the BAR600IVC Bariatric Bed and the TDX-SP Power Wheelchair. Following these reviews, the Expert shall certify whether Defendants' design control systems at the Corporate and Taylor Street facilities comply with the Act, its implementing regulations, and this Decree.

F. Within thirty (30) days after FDA's receipt of a report submitted by the

Defendants under paragraph 5(E), FDA shall notify Defendants in writing whether Defendants appear to be in compliance with the design control requirements set forth in paragraph 5(E) of this Decree. Upon receipt of FDA's written notification that Defendants appear to be in compliance with paragraph 5(E), Defendants may resume design activities, but not manufacturing or distributing products;

G. In the Expert's third report, he or she shall certify in writing to FDA: (1) that he or she has inspected Defendants' operations, processes, and controls that have not already been the subject of the Expert's prior reports and certifications at the Corporate and Taylor Street facilities; (2) whether Defendants have corrected all violations set forth in FDA's Inspectional Observations from all prior FDA inspections conducted since 2002 of the Corporate and Taylor Street facilities; and (3) based upon these comprehensive inspections, whether Defendants' operations at the Corporate and Taylor Street facilities comply with the Act, its implementing regulations, and this Decree. The Expert's certification report shall encompass, but not be limited to, an evaluation of the following:

i. Defendants' compliance with 21 U.S.C. §§ 351(h), 360j(f)(1), 352(t)(2), and 21 C.F.R. Parts 803 and 820;

ii. Defendants' procedures for their Corrective and Preventive Action ("CAPA") system including, but not limited to, analyzing quality control and assurance data to identify existing and potential causes of non-conforming product and other quality problems;

iii. Defendants' procedures for non-conforming product(s) including, but not limited to, the identification, documentation, evaluation, segregation, and disposition, including rework, of non-conforming product;

iv. Defendants' procedures for process validation including, but not limited to, validating with a high degree of assurance processes for which the results cannot be fully verified by subsequent inspection and test; and

v. Defendants' procedures for establishing an effective complaint handling system including, but not limited to, prompt review, evaluation and investigation of complaints that represent an event that must be reported to FDA under 21 C.F.R. Part 803.

H. Defendants report to FDA in writing the actions that they have taken to: (1) correct all violations brought to Defendants' attention by the Expert and set forth in FDA's Inspectional Observations from all prior FDA inspections of the Corporate and Taylor Street facilities since 2002; and (2) ensure that the methods used in, and the facilities and controls used for manufacturing, processing, packing, repacking, labeling, holding, and distributing the subject devices at the Corporate and Taylor Street facilities are operated and administered and will be continuously operated and administered in conformity with the Act, its implementing regulations, and this Decree.

I. Within thirty (30) days after FDA's receipt of a report submitted by the Defendants under paragraph 5(H), FDA representatives shall inspect Defendants' Corporate and Taylor Street facilities to determine whether the requirements of this Decree have been met and whether Defendants' operations are otherwise operated in conformity with current good manufacturing practice requirements, the Act, and its implementing regulations.

J. FDA notifies Defendants in writing within forty-five (45) calendar days after the conclusion of the inspection referred to in paragraph 5(I) above that Defendants appear to be in compliance with the requirements set forth in paragraphs 5(A)-(H) of this Decree.

6. Paragraphs 5 and 9 of this Decree shall not apply to the following:

A. Manufacturing, processing, packing, distributing, or holding a Taylor Street device that, as provided in this paragraph, a clinician has determined, through a clinical evaluation, is medically necessary for his/her patient. In order for a Taylor Street device to be considered medically necessary, a clinician must determine that it is necessary to meet the needs of a specific aspect of the patient's condition, and that the patient's needs could not be appropriately met by another manufacturer's device. Invacare shall provide a Taylor Street device to patients under these circumstances only if the following requirements have been and continue to be met: (i) evaluating clinicians and prescribing physicians have completed the Verification of Medical Necessity ("VMN"), attached hereto as Exhibit A-2; (ii) Invacare promptly provides FDA with copies of all VMNs for the first three (3) months following entry of this Decree; and (iii) Invacare maintains and promptly provides to FDA upon request copies of any VMNs executed after that date.

B. Manufacturing, processing, packing, or holding the subject devices, including any component, part, or sub-assembly, for the sole purpose of testing, verifying, or validating design changes, and subsequently distributing the subject devices that are used for the sole purpose of implementing a recall, including field corrective actions;

C. Manufacturing, processing, packing, holding, and distributing the Taylor Street devices for use in product demonstrations, workshops, and laboratories, provided that the subject devices are labeled, "For In-Office/In-Facility Patient Demonstration Use Only - Not for Sale;"

D. Manufacturing, processing, packing, holding, and distributing to testing

laboratories limited quantities of the subject devices used solely to develop, test, verify, or validate design changes or modifications, following receipt of FDA's written notification in paragraph 5(F);

E. Manufacturing, processing, packing, holding and distributing any Taylor Street device, including any component, part, raw material, accessory, or subassembly, solely for the purpose of: (i) providing routine service to a Taylor Street device that was already in the possession of a patient prior to the date of the entry of this Decree, or that was provided pursuant to paragraphs 6(A), 6(F), 6(G), or 6(I) of this Decree; (ii) servicing or repairing a Taylor Street device, repairing or replacing a Taylor Street component, part, or accessory for such devices, or replacing a Taylor Street device under warranty that cannot be repaired; (iii) providing a loaner device (for a period not to exceed ninety (90) days) while a patient's device is temporarily unavailable because it is being serviced or repaired;

F. Manufacturing, processing, packing, holding, and distributing Taylor Street devices, including any components, parts, or accessories: (i) to customers who had placed purchase orders or received written quotes prior to the date of the entry of this Decree, and (ii) for whom Invacare has documentation of the purchase order or written quote;

G. Manufacturing, processing, packing, holding, and distributing manual and power wheelchairs and seating systems from the Taylor Street facility to customers whose patients: (i) already own an Invacare manual or power wheelchair or seating system, (ii) are seeking a replacement wheelchair or seating system, and (iii) whose clinicians provide a written certification stating the patient is an existing Invacare wheelchair and/or seating system user and that the clinician requests a replacement product for the patient. Invacare shall provide

replacement wheelchairs and seating systems to patients only if the following requirements have been and continue to be met: (i) patients and their evaluating clinicians, or, when no clinicians are involved in the replacement of a Medicare Group 2 wheelchair, their providers, have completed the VMN, attached hereto as Exhibit A-1; (ii) Invacare has promptly provided FDA with copies of all VMNs for the first three months following entry of this Decree; and (iii) Invacare maintains and promptly provides to FDA upon request copies of any VMNs executed after that date. The replacement wheelchair or seating system shall be the identical Invacare model, unless the model has been discontinued, or, if the patient's needs have changed, a different model that is substantially similar to the patient's current wheelchair or seating system;

H. Manufacturing, processing, packing, holding, and distributing subject devices solely for the purpose of conducting clinical trials in accordance with 21 C.F.R. Part 812, provided that Defendants comply with all applicable laws and regulations relating to the manufacture and distribution of investigational devices;

I. Manufacturing, processing, packing, holding, and distributing Patriot Plus manual wheelchairs to the United States Department of Veterans Affairs under the current contract, which expires on January 14, 2013, and service parts, components, and warranty replacements for wheelchairs provided under this contract or any other existing contract with the Department of Veterans Affairs, for as long as they remain under warranty; and

J. Following receipt of FDA's written notification under paragraph 5(D) that Defendants appear to be in compliance with paragraph 5(C), manufacturing, processing, packing, holding and distributing to Invacare facilities other than the Taylor Street facility: (i) components, parts, raw materials, accessories, or sub-assemblies that are used to manufacture Invacare devices

produced at Invacare facilities other than the Taylor Street facility, or (ii) components, parts, raw materials, accessories, or sub-assemblies that are used to service or repair Invacare devices manufactured at facilities other than the Taylor Street facility.

7. Invacare may provide replacement components, parts, accessories, or sub-assemblies, and loaner devices to customers, contract service providers, and distributors for service or repair of Taylor Street devices, components, and sub-assemblies under paragraph 6(E) only if the following requirements have been met:

(a) Invacare shall send a copy of the notification letter attached hereto as Exhibit B to customers and contract service providers that service or repair Taylor Street devices and to distributors that sell components, parts, accessories, or sub-assemblies for service or repair to providers and facilities. Defendants shall not fulfill any requests for components, parts, accessories, or sub-assemblies until Defendants have received from the requesting customer, contract service provider, or distributor the certification required by the notification letter in Exhibit B;

(b) Any Taylor Street device furnished by Defendants to a customer under paragraph 6(E)(ii) shall be the identical device (same model) that Defendants received from the customer, or, if the model has been discontinued, a different model that is substantially similar to the patient's current device, and any loaner device provided under paragraph 6(E)(iii) shall be available to the customer for no more than ninety (90) days; and

(c) Invacare shall maintain records, and shall allow FDA access to such records upon request, of all service and repair components, parts, accessories, and sub-assemblies provided under paragraph 6(E), which records must include the following: (i) a record of the

notification letters sent to customers, contract service providers, and distributors; (ii) certifications provided by customers, contract service providers, and distributors that state that the parts, components, accessories, and/or sub-assemblies are only to be used for service and repair of Taylor Street devices; (iii) the names, addresses, and telephone numbers of the customers, contract service providers, and distributors receiving loaner devices or components, parts, accessories, and sub-assemblies for service and repair of Taylor Street devices; and (iv) records of all loaner devices and the components, parts, or accessories used to provide service.

8. Invacare shall provide Taylor Street devices, components, and sub-assemblies to customers under paragraph 6(F) only if the following requirements have been met: (a) Invacare shall send a copy of the notification letter attached hereto as Exhibit C to customers before shipping a Taylor Street device to fulfill any purchase order or written quote received prior to entry of the decree as set forth in paragraph 6(F), and (b) Invacare shall maintain records, and shall allow FDA access to such records upon request, of all such orders for products provided under paragraph 6(F), which records must include the following: (i) the date of the purchase order or written quote; (ii) the names, addresses, and telephone numbers of the persons/entities requesting the fulfillment of any purchase order or written quote; and (iii) the date that the purchase order or written quote was fulfilled.

9. Upon entry of this Decree, except as permitted in paragraphs 6, 7, and 8, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, are permanently enjoined

under the provisions of 21 U.S.C. § 332(a) from directly and indirectly doing and causing to be done any act that:

A. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, Taylor Street devices that are adulterated within the meaning of 21 U.S.C. § 351(h), and/or misbranded within the meaning of 21 U.S.C. § 352(t)(2);

B. Violates 21 U.S.C. § 331(k), by causing the Taylor Street devices to become adulterated within the meaning of 21 U.S.C. § 351(h), and/or misbranded within the meaning of 21 U.S.C. § 352(t)(2), while such devices are held for sale after shipment in interstate commerce;

C. Violates 21 U.S.C. § 331(q)(1)(B), by failing to furnish notification or other material or information to FDA for subject devices as required by 21 U.S.C. § 360i and the implementing regulations set forth in 21 C.F.R. Part 803.

10. After Defendants have complied with paragraphs 5(A)-(H) and FDA has notified Defendants in writing pursuant to paragraph 5(J), Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' operations not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of four (4) years thereafter, for a total of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in paragraph 5(B).

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' operations are operated and administered in continuous compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and to FDA by courier service or overnight delivery service, no later than twenty (20) calendar days after the date the audit inspections are completed. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty (30) calendar days, Defendants shall, within fifteen (15) calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. All Correction Schedules must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to an approved Correction Schedule. Within thirty (30) calendar days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions

taken by Defendants to correct the adverse Audit Report Observation(s). Within ten (10) calendar days after the conclusion of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection; the analysis of samples; a report or data prepared or submitted by Defendants, the Expert, or the Auditor pursuant to this Decree; or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions with respect to the Taylor Street devices. Such actions may include, but are not limited to, the following:

i. Cease designing, manufacturing, processing, packing, repacking, labeling, holding, storing, distributing, installing, servicing, importing and/or exporting Taylor Street devices;

ii. Revise, modify, or expand any report(s) prepared pursuant to the Decree;

iii. Submit additional notifications, reports, or any other materials or information to FDA;

iv. Recall, at Invacare's sole expense, adulterated and/or misbranded Taylor Street devices and components therein manufactured, distributed, and/or sold by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;

v. Issue a safety alert, public health advisory and/or press release; and/or

vi. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with the Act, its implementing regulations, and this Decree.

12. The following process and procedures shall apply when FDA issues an order under paragraph 11:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review,

Defendants shall continue to diligently implement FDA's order, unless the Court stays, reverses, or modifies FDA's order. Judicial review of FDA's order shall be made pursuant to paragraph 24.

D. The process and procedures set forth in paragraphs 12 (A)-(C) shall not apply to any order issued pursuant to paragraph 11 if such order states that, in FDA's judgment, the order raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of the order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Judicial review of FDA's decision under this paragraph shall be made pursuant to paragraph 24.

13. Any cessation of operations or other action described in paragraph 11 shall continue until Defendants: (a) receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may, therefore, resume operations; or (b) receive written authorization from the Court. The costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraphs 11 and 12, shall be borne by Invacare at the rates specified in paragraph 15.

14. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations at the Taylor Street and Corporate facilities and, without prior notice, take any other measures necessary to monitor and to ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted: access to buildings, equipment, in-process and finished

materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of the Taylor Street devices and the design of the subject devices. FDA will provide Defendants with a receipt for any samples taken pursuant to 21 U.S.C. § 374 and with copies of any photographs or video recordings made upon receipt of a written request by Defendants and at Defendants' expense. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

15. Defendant Invacare shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.55 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. FDA shall submit a reasonably detailed bill of costs to Defendant Invacare at the address specified in paragraph 20. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the court.

16. Within five (5) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree in the employee common areas at the Corporate and Taylor Street facilities and on Defendant Invacare's intranet Website in such a manner to ensure that it will be viewed by employees at the Corporate and Taylor Street facilities. Defendants shall ensure that the Decree remains posted in its employee common areas and on its intranet Website for as long as the Decree remains in effect.

17. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service, electronic mail, or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), with responsibility for the design, manufacture and/or distribution of the subject devices at or from the Taylor Street and Corporate facilities (hereinafter, collectively referred to as "Associated Persons"). For international Associated Persons, Invacare shall provide a copy of the Decree by personal service, electronic mail, or certified mail (restricted delivery, return receipt requested) within twenty-five (25) days. Within thirty (30) calendar days after the entry of this Decree, Defendant Invacare shall provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who have been provided a copy of this Decree pursuant to this paragraph and attaching documentation of the manner in which copies of the Decree were provided.

18. In the event that Defendant Invacare becomes associated, at any time after the entry of this Decree, with new Associated Person(s), Defendant Invacare shall within ten (10)

calendar days of the commencement of such association: (a) provide a copy of this Decree to each such Associated Person(s) by personal service, electronic mail, or certified mail (restricted delivery, return receipt requested); and (b) on a quarterly basis, notify FDA in writing, in accordance with paragraph 20, when, how, and to whom the Decree was provided. Defendants shall provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who have been provided a copy of this Decree pursuant to this paragraph, and attaching documentation of the manner in which copies of the Decree were provided.

19. Defendant Invacare shall notify the District Director, FDA Cincinnati District Office, in writing at least fifteen (15) calendar days before: (i) any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation that, in each case, may affect compliance with this Decree; (ii) the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the corporate structure of Defendant Invacare or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that, in each case, may affect compliance with this Decree. Defendant Invacare shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendant Invacare shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

20. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be addressed to the District Director, FDA Cincinnati District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097. All notifications, correspondence, and

communications required to be sent to Defendants by the terms of the Decree shall be addressed to Director of Consent Decree Compliance Task Force, Invacare Corporation, One Invacare Way, Elyria, Ohio 44036.

21. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on written notice of the United States in this proceeding, Defendant Invacare shall pay to the United States of America: (a) fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues; (b) an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; and (c) an additional sum in liquidated damages equal to twice Defendant Invacare's sale price of any shipments of adulterated or misbranded devices. The amount of liquidated damages imposed under this paragraph shall not exceed seven million dollars ($7,000,000) in any one calendar year. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

22. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendant Invacare shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

23. The parties may at any time petition each other in writing to modify any deadline provided herein, and if the parties mutually agree in writing to modify a deadline, such extension may be granted without seeking leave of the Court.

24. All decisions specified in this Decree shall be vested in the discretion of FDA and

shall be final. When contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary, capricious, abuse of discretion, or otherwise not in accordance with the law standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

25. During the course of negotiations preceding the entry of this Decree, FDA and Defendant Invacare exchanged documentation and communications regarding the potential need for Defendant Invacare to obtain premarket clearance from FDA for certain design changes and modifications to specific Taylor Street devices. With respect to the devices that were the subject of those documents and communications, if FDA subsequently determines and notifies Defendants that any or all of those design changes or modifications require additional premarket clearance, such notification shall not impede, limit, or restrict the Defendants from engaging in the activities or conduct authorized or permitted by Paragraph 6 of this Decree. Further, if FDA issues a notification that any or all of those design changes or modifications require additional premarket clearance, Paragraphs 5, 9, and 11 of this Decree shall not apply to those devices solely on the basis of the absence of premarket clearance with respect to any such devices. This paragraph applies only to those design modifications about which FDA and Defendants exchanged documents and communications between July 1, 2012 and the entry of this Decree.

26. If Defendants' operations have been maintained in a state of compliance with applicable laws and regulations and this Decree for at least sixty (60) months after satisfying all of their obligations under paragraph 5, Defendants may petition this Court for relief from this Decree, and the United States will not oppose such a petition.

27. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

So ordered the 21st day of December, 2012.

/s/Dan Aaron Polster
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree:

For the ~~Defendants~~:

GERALD B. BLOUCH
Individually and on behalf of Invacare Corporation as its President and CEO

ERNEST P. MANSOUR
Mansour, Gavin, Gerlack & Manos Co., L.P.A.
Cleveland, OH 44113
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